

REMARKS

In the present application, claims 1, 2 and 61-104 are pending and stand rejected in the non-final office action mailed March 3, 2006. Reconsideration of claims 1-2 and 61-104 in view of the remarks that follow is respectfully requested.

35 U.S.C. § 102 Rejections

"[A]n invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The claims must not be treated as "mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning." Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al., 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate.

Claims 1, 2, 66-68, 72 and 73 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,458,638 to Kuslich et al. Kuslich et al. discloses an end cap having retaining clips that project from the body of the end cap. The clips snap behind ribs 146 that extend into the interior space of the cage at the end opening of the cage. The ribs 146 extend into and obstruct the same opening in which the body of the cap is positioned. Thus, Kuslich discloses a cap in which the clips are provided with a length to engage a structure located in the opening in which the cap positioned. There is no disclosure that the retaining clips have any length to engage any structure that is not located within the capped end opening. Furthermore, as shown in Fig. 18, the clips extending from the body of the cap are not elongate, but rather are significantly wider than they are long.

In contrast, claim 1 recites "an occlusion body sized and shaped for blocking the opening; and an elongate anchor projecting from said occlusion body, said anchor

including a first end attached to said occlusion body and an opposite second end having a lip for engaging the thru-hole, said anchor having a length which reaches from said occlusion body to the thru-hole when the cap is inserted into the opening and said lip is engaged to said thru-hole." Accordingly, Kuslich fails to disclose claim 1 and withdrawal of this basis of the rejection is respectfully requested. Claims 2, 66-68, 72 and 73 depend from claim 1 and are allowable at least because claim 1 is allowable.

Claims 75-81 and 87-92 were rejected under 35 USC §102(e) as being anticipated by U.S. Patent No. 5,702,451 to Biedermann et al. Biedermann et al. is directed to a space holder for an intervertebral space including a jacket member 1 and various stops 11, 13, 16, & 22. Each of the stops includes radially extending prongs 15 structured to mate with corresponding recesses 9, 10 at the ends of the jacket member 1 so that the jacket member 1 may be selectively sized to fill a desired intervertebral space. The Examiner asserts that in Figs. 6-11 the cap therein includes an edge portion 20 structured to engage the jacket 1 to cap the end.

Applicant traverses this assertion and submits that edge portion 20 is not structured to engage the jacket member 1. Rather, when engaged to jacket member 1, ring 12 is positioned in the end of the jacket and edge portion 20 extends away from the interior of jacket member 1 in order to provide an inclined end to engage an adjacent vertebral body. This configuration is supported by Beidermann et al. where it states that "[i]n operation both embodiments, i.e. the members 19 and 22, respectively, are inserted into the jacket in the same manner as the previously described embodiments so that the projecting noses 15 of the ring 12 lie in the lowermost parts of the V-shaped recesses 9, 10 and the prongs extend outwardly beyond the edge of the jacket" (See Col. 3, Lines 21-26). Furthermore the specification provides that: "[i]n the embodiment shown in FIGS. 6 and 7 the prongs 21 or 21' may be cut to different lengths, for example along the broken line 23 to form a wedge-shaped insert. Similarly the edge of the member 22 can be cut so that the predetermined angle between the outer edge and the plate-shaped ring 12 is varied. In this manner it is possible to obtain, using few basic members, space holders having different wedge angles." (See Col. 3, Lines 26-33) The fact that the prongs may be cut at various angles to provide different wedge angles makes clear that the edge

portion 20 is not disclosed to extend into the jacket member but rather away from the jacket member since cutting the prongs 21, 21' in an angled relationship to ring 12 would not have a purpose if the prongs were to engage with the interior of the jacket member.

Independent claim 75 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including a flat outer wall lying in a plane; and an elongate anchor projecting from said occlusion body in a direction transverse to the plane, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends from said occlusion body to the second end, wherein said second end is structured and configured to engage the fusion device at a location spaced from the plane. As discussed above, Biedermann et al. reference fails to disclose the elements arranged as recited in claim 75. Namely, Biedermann et al. discloses that the second end of prongs 21, 21' is structured and configured to engage a vertebral body, not the jacket member 1. Therefore, independent claim 75 distinguishes Biedermann et al and is patentable. Additionally, Applicant submits that each of claims 76-81, which either directly or indirectly depend from claim 75, are patentable for at least the reasons supporting the patentability of claim 75.

Independent claim 87 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including at least one osteogenic aperture extending therethrough; and an elongate anchor projecting from and extending transversely to said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends axially from said occlusion body to the second end, wherein said second end is structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Again, the Biedermann et al. is directed to a cap where edge portion 20 is structured to engage a vertebral body with prongs 21, 21', and the prongs extend away from jacket member 1. Therefore, independent claim 87 is patentable over Biedermann et al. and withdrawal of the rejection is respectfully requested. Furthermore, each of claims 88-92, which depend

either directly or indirectly from claim 87, is patentable for at least the reasons supporting the patentability of independent claim 87.

35 U.S.C. § 103 Rejections

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." Manual of Patent Examining Procedure (MPEP) §2142 (citing *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Moreover, the suggestion/motivation to combine or modify under §103 needs to be specific. Where a "statement is of a type that gives only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it ... [s]uch a suggestion may make an approach 'obvious to try' but it does not make the invention obvious." *Ex parte Obukowicz*, 27 USPQ2d 1063, 1065 (U.S. Pat. and Trademark Off. Bd. of Pat. App. & Interferences 1993) (citations omitted).

Claims 75 and 77-81 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuslich et al. Independent claim 75 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including a flat outer wall lying in a plane; and an elongate anchor projecting from said occlusion body in a direction transverse to the plane, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends from said occlusion body to the second end, wherein said second end is structured and configured to engage the fusion device at a location spaced from the plane.

The Examiner asserts "that it would have been *prima facie* obvious to make the cap of Kuslich et al. at least partially flat on the outer surface when used on the same end

as cap (18") of Kuslich for the same reasons that Kuslich does the same in that embodiment." As noted above, in order to establish a *prima facie* case of obviousness, a reference must, amongst other requirements, teach or suggest all the claim limitations. Manual of Patent Examining Procedure (MPEP) §2142. As discussed above with respect to claim 1, Kuslich et al. fails to teach or suggest a cap including an elongate anchor including a second end structured and configured to engage the fusion device at a location spaced from the plane. Therefore, a *prima facie* case of obviousness has not been established because the reference does not teach or suggest all the claim limitations per the requirements of the MPEP § 2142. As such, Applicant respectfully requests that the obviousness rejection of claim 75 be withdrawn. Furthermore, Applicant submits that each of claims 77-81 is patentable for at least the reasons supporting the patentability of independent claim 75.

Claims 61, 62, 65, 74, 76, 87, 88, 93, and 97 were rejected under 35 USC §103(a) as being unpatentable over Kuslich et al. in view of Biedermann et al. or PCT Publication No. WO 91/06261 to Ray et al. The Examiner asserts that Kuslich et al. meets the claim language but for disclosing apertures in the cap as claimed. However, the Kuslich et al. reference combined with the Biedermann et al. and Ray et al. are set forth as making the inclusion of apertures in the cap obvious. "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 23 USPQ2d, 1783-84 (Fed. Cir. 1992) (holding that a combination of references does not render a claim obvious due to a lack of suggestion or motivation to combine or modify). As a corollary, the patent office has recognized that "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." Manual of Patent Examining Procedure (MPEP) § 2143.01. MPEP § 2143.01 also states that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."

Applicant submits that the Examiner's suggestion to modify Kuslich et al. is contrary to the teachings of Kuslich et al. and also would render it unsuitable for its intended purpose.

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Namely, leading end cap 18 covering axial opening 40 "prevents disk material from migrating through axial opening 40 into chamber 24 during insertion of the implant 10 as well as during the patient's recovery phase." (See Col. 6, Lines 57-61). Additionally, "like leading end cap 18, trailing end cap 20 prevents disk material from entering chamber 24." (See Col. 7, Lines 21-24). Therefore, Kuslich et al. teaches away from apertures in the end cap, and if apertures were added to leading end cap 18 or trailing end cap 20, the device of Kuslich et al. would be unsatisfactory for its intended purpose since disk material could enter chamber 24 through the cap.

Claim 61 depends from claim 1 and is patentable at least for the reasons claim 1 is patentable. Furthermore, claim 61 recites that the occlusion body includes osteogenic apertures, said apertures sized to permit bone ingrowth and protein ingress. As noted, Kuslich et al. teaches away from the modification to include this feature and the proposed modification would render the end cap disclosed therein unsatisfactory for its intended purpose. Therefore, withdrawal of this basis of the rejection is respectfully requested. Additionally, claims 62 and 65, which depend from claim 61, are submitted to be patentable for at least the reasons supporting the patentability of claim 61. Claim 74 depends indirectly from claim 1 and is patentable for the reasons provided from claim 1, and is also patentable since the modification of the Kuslich et al. reference to include apertures in the leading and trailing caps would render the cap disclosed therein device unsatisfactory for its intended purpose.

Claim 76 depends from claim 75 and is patentable at least for the reasons claim 75 is patentable as provided above. In addition, claim 76 recites that the occlusion body defines at least one osteogenic aperture to permit bone growth through said occlusion body. Claim 76 is further submitted to be patentable for the same underlying reasons provided above with respect to claim 61.

Claim 87 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body including at least one osteogenic aperture extending therethrough; and an elongate anchor projecting from and extending transversely to said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends axially from said occlusion body to the second end,

wherein said second end is structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Claim 87 is submitted as patentable because Kuslich et al. teaches away from the addition of holes to the leading and trailing caps since Kuslich et al. teaches end caps that are solid to prohibit disk material from entering the interior of the fusion device. Additionally, Kuslich et al., as discussed above, fails to disclose an elongate anchor including a second end, wherein said second end is structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Therefore, claim 87 is patentable and withdrawal of the rejection thereof is respectfully requested. Claims 88, 93, and 97 depend from claim 87 and are patentable at least for the reasons supporting the patentability of independent claim 87.

Claims 1, 2, 61-64, and 86 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al in view of Kuslich et al. The Examiner asserts that Biedermann et al. discloses a cap with an occlusion body including an anchor projecting therefrom. Furthermore, in view of the teaching of Kuslich et al., the Examiner contends that it would have been obvious to include a lip or barb on the anchor to hold it to the jacket member. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP §2143.01. As indicated above, edge portion 20 extending from ring 12 of Biedermann et al. is not structured to engage with cage member 1. However, as one skilled in the art would recognize, edge portion 20 is structured to extend away from cage member 1 such that prongs 21 and 21' can engage a vertebral body. There would be no desirability to add a lip or other cage engaging structure on the ends of prongs 21, 21'. One having ordinary skill in the art would recognize that adding this feature thereto would increase structure without improving function, thereby increasing manufacturing costs and resultantly making the added feature undesirable. In fact, one skilled in the art may further recognize that adding a lip to prongs 21, 21' could render these structures unsatisfactory for their intended purpose, because the addition of a lip or barb could impede engagement with a vertebral member. Therefore, there is no motivation or desirability to make the modification to the prongs in Biedermann et al.

proposed in the office action, and Applicant respectfully requests withdraw this rejection of claims 1, 2, 61-64, and 86.

Claims 69, 82, and 83 were rejected under 35 USC §103(a) as being unpatentable over Kuslich et al. in view of U.S. Patent Publication No. 2002/0138144 to Michelson. Claim 69 depends from claim 1, and each of claims 82 and 83 depend directly and indirectly, respectively, from independent claim 75. Based on their dependency therefrom, each is submitted as patentable, since as indicated above, the Kuslich et al. reference fails to disclose all of the claim limitations of independent claims 1 and 75. Accordingly, withdrawal of this basis of the rejection of claim claims 69, 82 and 83 is respectfully requested.

Additional reasons supporting the patentability of claims 69 and 83 exist. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP § 2143.01. The Kuslich et al. reference discloses that body 12 is preferably formed from titanium and/or its alloys because of its noncorrosiveness and fatigue resistance. (See Col. 4, Lines 1-4). The reference further discloses that end caps 18, 20 are preferably formed of high density polyethylene because among other characteristics it has a "slippery touch". (See Col. 7, Lines 14-16). This characteristic is valuable since the end caps may come in touch with epidural tissue which would become irritated if the surface were not "slippery". (See Col. 7, Lines 16-19). If Kuslich et al. used biodegradable caps, then the ends of titanium body 12 would become exposed, coming into contact with epidural tissue and causing irritation thereof, making the device unsatisfactory for its intended purposes. Therefore, Applicant respectfully requests withdrawal of this rejection of claims 69 and 83 for these additional reasons.

Claims 82 and 83 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Michelson (U.S. 2002/0138144). Each of claims 82 and 83 depend directly and indirectly, respectively, from independent claim 75. Based on their dependency therefrom, each is submitted as patentable, since as indicated above, Biedermann et al. fails to disclose all of the claim limitations of independent claim 75. Additionally, in regard to claim 83, one having ordinary skill in the art would recognize

amongst other reasons, that member 11 is placed into jacket member 1 to provide structural support for the jacket member and to engage a vertebral body. If member 11 were biodegradable then jacket member 1 would lose the support provided by member 11. In view of the forgoing arguments, Applicant submits that each of claims 82 and 83 is patentable over the combination of Biedermann et al. in view of Michelson (U.S. 2002/0138144).

Claim 94 was rejected under 35 USC §103(a) as being unpatentable over Kuslich et al., Biedermann et al., and Ray as applied to claims 61, 62, 65, 74, 76, 87, 88, 93, and 97 in further view of Michelson (2002/0138144). Claim 94 depends directly from independent claim 87 and is submitted as patentable for at least the reasons submitted herein supporting the patentability of independent claim 87. Additionally supporting the patentability of claim 94, as already submitted herein, is that Kuslich et al. and Biedermann et al. teach away from biodegradable end caps. Applicant therefore submits claim 94 is patentable and respectfully requests withdrawal of this ground of rejection.

Claim 70 was rejected under 35 USC §103(a) as being unpatentable over Kuslich in view of U.S. Patent No. 6,605,089 to Michelson. Claim 70 depends directly from independent claim 1 and is patentable for at least the reasons supporting the patentability of independent claim 1 as discussed above.

Claim 84 was rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Michelson (U.S. Patent No. 6,605,089). Claim 84 depends from independent claim 75 is patentable at least for the reasons claim 75 is patentable as discussed above.

Claims 71 and 85 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. and Michelson (6,605,089) as applied to claim 84 above in further view of French Patent No. 2,710,519 to Robine. Claim 71 depends from claim 1, and claim 85 depends from claim 84. Claims 71 and 85 are patentable for the same reasons supporting the patentability of claims 1 and 84 and Applicant respectfully requests withdrawal of the rejection thereof.

Claim 96 was rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Robine. Claim 96 depends from claim 87, which is

patentable for the reasons provided above. Therefore, withdrawal of this basis of the rejection of claim 96 is respectfully requested.

Claim 95 was rejected under 35 USC §103(a) as being unpatentable over Kuslich et al., Biedermann et al., and Ray as applied to 61, 62, 65, 74, 76, 87, 88, 93, and 97 above, and in further view of Michelson (U.S. Patent No. 6,605,089). Claim 95 directly depends from claim 87 which is patentable for reasons asserted herein. Thus, claim 95 is submitted as patentable at least for the reasons supporting the patentability of independent claim 87 and withdrawal of this basis of the rejection is respectfully requested.

Claims 98-103 were rejected under 35 USC §103(a) as being unpatentable over Biedermann et al. in view of Michelson (U.S. Patent No. 6,650,089). Independent claim 98 is directed to a cap for blocking an opening of a hollow fusion device, comprising an occlusion body sized and shaped for blocking the opening, said occlusion body being composed of a porous material; and an elongate anchor projecting from and extending transversely to said occlusion body, said anchor including a first end attached to said occlusion body and an opposite second end, said anchor having a length which extends axially from said occlusion body to the second end, wherein said second end is structured and configured to engage the fusion device at a location axially spaced from said occlusion body.

The prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2142. As discussed above, the Biedermann et al. reference does not suggest or teach a cap including an elongate anchor with a second end structured and configured to engage the fusion device at a location axially spaced from said occlusion body. Instead, edge 20 and prongs 21, 21' are structured and configured to extend away from jacket member 1 (fusion device) to engage a vertebral body. Thus, the Applicant contends that a *prima facie* case of obviousness in regard to claims 98-103 has not been made and respectfully requests withdrawal of the rejection therefrom.

Claim 104 was rejected under 35 USC §103(a) as being unpatentable over Biedermann and Michelson as applied to claims 98-103 and further in view of Kuslich et al. Claim 104 is submitted as patentable at least for the reasons submitted supporting the

patentability of claims 98-103. Furthermore, as discussed above, Applicant contends that one having ordinary skill in the art would recognize that there is no motivation or suggestion to add lips or barbs to edge 20 or prongs 21, 21' as such addition would increase structural complexity without gaining a structural advantage. Withdrawal of this basis of the rejection of claim 104 is respectfully requested.

Claims 71, 85 and 96 were rejected under 35 USC §103(a) as being unpatentable over Kuslich et al. and Michelson (U.S. Patent No. 6,605,089) as applied to claim 70 above, and further in view of Robine. Each of claims 71, 85, and 96 is submitted as patentable at least for the reasons supporting the patentability of each underlying base claim 1, 75, and 87 as discussed above. Additionally, "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." Manual of Patent Examining Procedure (MPEP) § 2141.02. Moreover, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." Manual of Patent Examining Procedure (MPEP) § 2143.01. As submitted above, Kuslich et al. is directed to end caps that are structured to keep disk material from migrating into chamber 24 during insertion of the implant as well as during the recovery phase. (See Col. 6, Lines 58-61; Col. 7, Lines 22-24). Adding a threaded hole to the end caps of Kuslich et al. is contrary to the teachings in Kuslich et al. since disk material could migrate into the chamber through the threaded hole. Therefore, Applicant submits that each of claims 71, 85, and 96 is patentable over the Kuslich and Michelson (U.S. Patent No. 6,605,089) in view of Robine, and withdrawal of this basis of the rejection is respectfully requested.

Reconsideration of the present application including claims 1-2 and 61-104 is hereby respectfully solicited. The Examiner is welcome to contact the undersigned to resolve any outstanding issue with regard to the present application.

Respectfully submitted

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